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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,687	10/05/2000	Stephen M. Allen	BB1162 US NA	1467
7590 04/20/2004 Connolly Bove Lodge & Hutz P.O BOX2207 Market Street WILMINGTON, DE 19899			EXAMINER WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/679,687	ALLEN ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
4a) Of the above claim(s) 31 and 33 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 25-30, 32 and 34 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 05 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/23/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 23 October 2003 has been entered. Claims 1-24, 31 and 33 are canceled. Claims 25-30, 32 and 34 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office action.

Withdrawn Objections and/or Rejections

Title

The objection to the title as set forth at page 2 of the previous Office Action (21 April 2003) is *withdrawn* in view of the amendment which introduced a new title (23 October 2003).

35 U.S.C. § 112, first paragraph-Enablement.

The rejection of Claim 34 under 35 U.S.C. 112, first paragraph, as set forth at pages 9-10 of the previous Office Action (21 April 2003), is *withdrawn*. Applicants have explained that one of skill in the art can produce multicellular plants from transfected plant cells without undue experimentation (page 5, 23 October 2003).

35 USC § 112, first paragraph – Written Description.

The rejection of Claim 34 under 35 U.S.C. 112, first paragraph, as set forth at pages 10-11 of the previous Office Action (21 April 2003), is *withdrawn*. Applicants have explained that

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one of skill in the art can produce multicellular plants from transfected plant cells without undue experimentation (page 5, 23 October 2003), and that this is discussed in the Specification at pages 1 and 2. Furthermore, the incorporated transporter is well-described as SEQ ID NO: 1 and 2.

Maintained Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 25-30, 32 and 34 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under 35 U.S.C. § 101 are set forth at pp. 3-9 of the previous Office Action (21 April 2003). Claims 25-30, 32 and 34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (21 April 2003), one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to a nucleotide that encodes a protein that possesses approximately 30-40% homology to known proteins, such as a sucrose transporter in rice (Hirose, T., 1997, Accession No. BAA24071) and the carrot sucrose/H⁺ symporter protein (Sturm, A., 1999, Accession No. CAA76367). As discussed in the previous Office Action (page 3), no well-established utility exists for newly isolated complex biological molecules. The specification does not disclose experiments that impart *any* function for the claimed nucleotide in the context of the cell or organism. The specification does not teach the skilled artisan how to use the symporter or transporter peptide for any unique or specific purpose. Nor does the specification predict or discuss a specific function for the claimed polynucleotide. For example,

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there is no disclosure of the use of a substrate for the transporter, or changes in transporter-mediated processes in transfected cells, or the phenotypes of "knock-in" or "knock-out" organisms, or of flux assays, or of diseases caused by an overactivity or underactivity of the transporter. The skilled artisan is not provided with sufficient guidance to use the claimed polynucleotides for any purpose.

Applicants argue (pages 4-5, 23 October 2003) that the nucleotide of the instant Specification encodes a polypeptide that has homology to a sucrose transporter with a specific function (*AgSUT1* in: Lemoine, R., 2000, *Biochim. Biophys. Acta.*, 1465: 246-262; Also: Noiraud, et al, 1999, Accession No. GI4091891). However, the disclosed polypeptide of the Instant Specification and the claimed polynucleotides encoding it are currently unidentified molecules. Very little information is given in the Specification about specific substrates of the polypeptide encoded by the claimed polynucleotide(s), or of kinetics, or of disease states due to mutant polynucleotides. Applicants discuss sequence and structural homologies between the polypeptide of SEQ ID NO: 2 in the instant Specification and the *AgSUT1* transporter disclosed in *Lemoine* paper. However, despite having some well-conserved structural similarities that might allow the peptide of SEQ ID NO: 2 to be put in the same broad class of transporters as Accession No. GI4091891, the percent identities between SEQ ID NO: 2 and Accession No. GI4091891 are moderate to low at 35-39% (Appendix B, 23 October 2003). Additionally, the *AgSUT1* transporter in the *Lemoine* paper has not been assigned a specific function. This low homology combined with a lack of function for the closest homologous transporter indicates that a specific function cannot be attributed to the transporter encoded by the claimed SEQ ID NO: 1. Even if the claimed polynucleotide were shown to encode a sucrose transporter family member,

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further evidence of a function specific to the claimed nucleotide would be needed, since this family is large and diverse (Bisson, L. and Coons, D., 1993, Crit. Rev. Biochem. Mol. Biol., 28(4): 259-308).

Applicants discussed Wilhelm, et al (1999, Crop Sci., 39: 1733-1741) in terms of a presumed function for sucrose transporters (page 4, 23 October 2003). It is not known how the transporter of SEQ ID NO: 2 is related to or discussed in this publication. The Applicant is asked to be more specific about where SEQ ID NO: 2 or the claimed encoding nucleic acid is discussed in that publication.

Brenner v. Manson (383 US 519) contemplated the utility of new inventions and concluded:

"The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field (Justice Fortas, writing for the majority)."

As stated in the conclusion: "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion (Fortas)."

Applicants have not indicated or predicted a substantial or specific utility for the claimed polynucleotide. Furthermore, since the claimed polynucleotides have low homology to known transporters, homology or relatedness cannot be used to assign utility to the claimed polynucleotide.

Applicants argue (page 5, 23 October 2003) that once the polypeptide of SEQ ID NO: 2 is expressed in cells, "activity may be determined using routine tests." However, the Patent Office makes clear that the usefulness of new polypeptides and polynucleotides does not include

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“entry point” and speculative experiments (Federal Register, 2001, 66: 1094). There is no evidence that the protein disclosed in the instant Specification functions as a transporter. However, even if it were established as such, additional specific functional assays would be needed since these families of proteins are very large and enormously varied (Bisson, L. and Coons, D., 1993, Crit. Rev. Biochem. Mol. Biol., 28(4): 259-308). Transporters bind to and translocate a wide-variety of small molecules in organisms. Even closely-related family members sometimes work very differently and have different specific functions in the organism. For example, Bisson, *et al*, studied yeast transporter knock-out phenotypes, and found little correlation between homology and the substrate transported (Bisson, et al, 1993, Crit. Reviews Biochem. Mol. Biol. 28: 259). For example, *Gal2* and *Hxt4* displayed 83.7% homology, but *Gal2* appears to transport Galactose, while *Hxt4* appears to transport Glucose (based on knockout phenotype- compare Table 1 and Table 2A). Mutant transporters are often incapable of binding to or translocating substrates, for example. These examples and others demonstrate that one skilled in the art would not know the utility and function of the polypeptide disclosed in the instant disclosure, even if it *were* classified as a transporter because, as discussed in the related art above, transporters mediate a variety of cellular functions including regulation of membrane potentials and absorption and secretion of molecules and ions across cell membranes.

Regarding Claims 25(a) and 26, the specification does not enable variants of SEQ ID NO: 2. The claims are directed to variants of SEQ ID NO: 2. Claims 25(a) and 26 read on peptides that are at least 90% identical to SEQ ID NO: 2.

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Applicants argue that "the specification coupled with the extensive knowledge about conserved residues present in the art provides specific guidance to one of ordinary skill as to which structures are likely to have enzyme activity. [] With the expressed polypeptide, activity may be determined using routine tests."

However, the specific activities of the claimed protein are not disclosed. Furthermore, there is no discussion or working examples disclosed that teach exactly which amino acids are necessary to maintain the functional characteristics of all polypeptides as claimed. This combined with the fact that the closest homologous protein has not itself been assigned a function results in a lack of function for all encompassed variants.

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation required to determine how to use the transporter of SEQ ID NO: 2 and all variants of SEQ ID NO: 2, the lack of direction or guidance in the specification regarding same - e.g., the lack of guidance regarding a *specific* activity of SEQ ID NO: 2, the lack of working examples to all variants of SEQ ID NO: 2, the state of the art showing the unpredictability of function based on structural similarity of transporter polypeptides, and the breadth of the claims which embrace innumerable variants of SEQ ID NO: 2, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

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Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is

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703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

4/14/04


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